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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <i>LD</i>
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EXAMINER
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ART UNIT	PAPER NUMBER <i>7</i>
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/423,622

Applicant(s)

MULLER ET AL

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I. claim(s) 1-3 and 7-12 drawn to the method for neuronal regeneration by prevention of basal membrane element formation by an inhibitor substance wherein the basal membrane elements are listed in claims 3 and 12.

Group II, claim(s) 1-2, 4-10, and 13-14 drawn to the method for neuronal regeneration wherein basal membrane element formation is prevented by inhibitor substances as listed in claims 4-5 and 13-14.

Group III. claim(s) 1 and 6, drawn to the method for neuronal regeneration by prevention of basal element formation wherein an inhibitor substance is applied in combination with a growth stimulating substance.

Group IV, claim(s) 15 and 16-17, drawn to a neuronal regeneration product comprising of an inhibitor substance preventing basal membrane formation in combination with a neuronal growth stimulating substance applied in therapeutically effective amounts.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Claims 1 and 15 are anticipated by prior art. US patent 5,082,926 describes a polypeptide fragment of collagen IV and antibodies specific thereto which inhibit basal lamina formation.

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This patent discloses that the collagen IV-derived peptide has the ability to promote nerve regeneration and specifies that the peptide can be used in a clinical setting to promote regeneration of damaged nerves. Therefore, claims 1 and 15 lack a special technical feature and cannot share one with the other claims.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species wherein the basal element building elements are as follows:

Ia. collagen IV

Ib. laminin

Ic. entactin

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The following claim(s) are generic: 1-2, 4-11, and 13-17.

**If applicant selects Group I-IV, one species from the basal membrane element group must be chosen to be fully responsive.**

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species wherein the inhibitor substances are as follows:

- Id. collagen IV antibody
- Ie. laminin antibody
- If. entactin antibody
- Ig. Fe-chelating agents
- Ih. prolyl-4-hydroxylase
- Ii. lysine-hydroxylase
- Ij. 2-oxoglutarate
- Ik. antisense oligonucleotides
- Il. oligonucleotide analogs
- Im. N-oxaloglycine
- In. Zn salts
- Io. 5-arylcarbonyamino derivatives
- Ip. 5-arylcarbamoyl derivatives
- Iq. 2-carboxylate

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- Ir. 2,5 dicarboxylate
- Is. 5-acyl sulfonamides
- It. 2,4 dicarboxylate
- Iu. 3,4'-bipyridine
- Iv. 5 amino-6-(1H)-one
- Iw. 1,6-dihydro-2-methyl-6-oxo-5-carbonitril
- Ix. 2,2'-bipyridine
- Iy. 5,5'-dicarboxylic acid
- Iz. 4,4'-dicarboxylic acid ethyl ester
- Ila. 4,4'-dicarboxylic acid ethyl amide
- Ilb. 3,4'-dihydroxybenzoate
- Ilc. proline
- Ild.  $\beta$ -aminopropionitrile
- Ile. desferrioxamine
- Ilf. anthracyclines
- Ilg. 2,7,8-trihydroxy anthraquinones
- Ilh. fibrostatin-C
- Ili. coumalic acid
- Ilj. 5-oxaproline

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The following claim(s) are generic: 1-3, 6-12, and 15-17.

**If applicant selects Group II, one species from the inhibitor substance group must also be chosen to be fully responsive.**

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The request for corrected notification of acceptance filed 03 March 2000 has been matched to the file. Immediately subsequent to the mailing of this Office Action, the application will be forwarded to PCT division for action on the request.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

beb

August 17, 2000